



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,822	10/24/2005	Mark Brister	PA1187	3938
28390 7590 07/16/2007 MEDTRONIC VASCULAR, INC. IP LEGAL DEPARTMENT 3576 UNOCAL PLACE SANTA ROSA, CA 95403			EXAMINER ADAMS, AMANDA S	
			ART UNIT 3731	PAPER NUMBER
			NOTIFICATION DATE 07/16/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

H

Office Action Summary	Application No. 10/531,822	Applicant(s) BRISTER, MARK	
	Examiner Amanda Adams	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 3-6, 8-10, 26, and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Castro et al (US 6,616,765).
2. Regarding claims 1 and 6, Castro discloses the invention substantially as claimed comprising a catheter, a balloon operably attached to the catheter, and a stent disposed on the balloon (col. 1, lines 19-27). Castro also discloses that the stent has a first region and a second region; a first coating section which is disposed on the first region and comprising a first polymer; a second coating section which is disposed on the second region and comprising a second polymer, wherein the first region and second region are discrete, and the first coating section and second coating section are discrete (col. 17, line 60 – col. 18, line 3; figure 13F).
3. Regarding claims 3, 4, 8, and 9, Castro discloses that the first coating section includes a first therapeutic agent and that the second coating section includes a second therapeutic agent (col. 17, line 64 – col. 18, line 2).
4. Regarding claims 5 and 10, Castro discloses that the first and second regions can form a spotted pattern (figure 13F).
5. Regarding claims 26 and 27, Castro discloses that the stent comprises stent segment (figure 6A) and that the first region extends longitudinally across a plurality of

the stent segments (using the embodiment where the first region is that covered by [10] in figure 10A, and applying that to more than one stent segments on the stent in figure 6A, the first regions extends across a plurality of the segments over a longitudinal segment of the stent).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al (US 6,616,765) in view of Boneau (US 5,292,331).

8. Regarding claim 22, Castro discloses a stent with a first discrete region and a second discrete region (fig. 13A-13H), a first polymer including a first therapeutic agent, the first polymer disposed on and blanketing the discrete first region as a first coating section, and a second polymer including a second therapeutic agent, the second polymer disposed on and blanketing the discrete second region as a second coating section (col. 17, line 60 – col. 18, line 3). Castro also discloses that the first coating section and the second coating section are discrete (figs. 13F-13H, where [10] and [80] are the first and second polymers) and that the coating can be applied in a longitudinal direction (fig. 10A [10]). Castro fails to disclose that the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state.

However, Boneau teaches that a stent can have a structure such that the longitudinal

Art Unit: 3731

length of its struts is greater than its diameter when in an expanded position (fig. 5).

Therefore it would have been obvious to apply the coatings as disclosed by Castro to the stent of Boneau in order for the first discrete region to have a length greater than the diameter of the expanded stent. The coatings and positioning of coatings disclosed by Castro can be applied to any stent, and choosing the stent design of Boneau provides a stent that is long enough to support a chosen length of blood vessel in a patient.

9. Regarding claim 23, Castro further discloses that the first and second discrete regions are separated by a bare section (fig. 13F).

10. Regarding claims 24 and 25, Castro discloses the invention substantially as claimed above. However, due to lack of criticality in the applicant's specification, the distances between discrete coated regions serve no particular purpose and provide no additional benefit as opposed to any other specific distances. Therefore, it would have been obvious to arbitrarily choose these distances because they are both within the scope of the size of an intravascular stent.

11. Regarding claims 11 and 18, Castro discloses the invention substantially as claimed above, further disclosing mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (col. 11, lines 7-13), applying the first polymer solution to the first region to form a first coating section blanketing the first region (col. 14, lines 65-67), mixing a second polymer and second therapeutic agent with a solvent to form a second polymer solution (col. 17, line 62 – col. 18, line 4), and applying the second polymer solution to the second region to form a second coating section blanketing the second region (col. 18, lines 14-32). Castro fails to specifically

Art Unit: 3731

disclose that the solvent mixed with the second polymer and second therapeutic agent is a second solvent, but teaches that it could be a second solvent (col. 11, lines 55-59; col. 12, lines 20-24). Choosing a solvent based on the polymer chosen implies that if a second polymer is used, then a second solvent will also be used. Further, Castro discloses that all other variables of the second composition are different than that of the first, so it would have been obvious to choose a second solvent when forming the second polymer solution.

12. Castro further discloses that the first and second coating sections are discrete, and that the first region has a longitudinal length (figs. 13 and 10), however Castro fails to disclose that the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state. However, Boneau teaches that a stent can have a structure such that the longitudinal length of its struts is greater than its diameter when in an expanded position (fig. 5). Therefore it would have been obvious to apply the coatings as disclosed by Castro to the stent of Boneau for the reasons provided above with respect to claim 22.

13. Regarding claims 12 and 19, Castro further discloses the first and second polymer solutions may be applied simultaneously (col. 17, lines 61-64).

14. Regarding claims 13 and 20, Castro discloses curing the first and second polymer solutions (col. 9, lines 64-65).

15. Regarding claims 14 and 21, Castro further discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (col. 6, lines 24-35).

Art Unit: 3731

16. Regarding claims 15-17, Castro further discloses mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45).

Response to Arguments

17. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

18. It can be said that the discrete first and second regions as disclosed by Castro are blanketed with the polymer coating because the regions can be arbitrarily chosen to be confined to the area that is covered by the polymer coating or an area less than the coating. To meet the limitations of the amended claims regarding the longitudinal length of the discrete first region, the stent of Boneau has been added to the rejection to show that the method and designs of Castro's coatings can be used on a stent that meets those structural limitations of length in relation to diameter.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 7/6/07


(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER
07/09/07